

REMARKS

The Examiner has required a restriction under 35 U.S.C. § 121 to one of the following five separate inventions:

Group I: **Claims 1-18**, drawn to a method for directly delivering a substance comprising bolus administration of a substance into the dermis, whereby the administered substance has at least **one improved pharmacokinetic parameter relative to the same pharmacokinetic parameter produced upon administration of the same substance subcutaneously**, classified in class 604, subclass 500.

Group II: **Claims 19-30**, drawn to a method of administering a **pharmaceutical substance intradermally through one or more microneedles over a time period of not more than ten minutes to obtain absorption of the substance in the dermis**, classified in class 604, subclass 506.

Group III: **Claims 31-52**, drawn to a method for administering a macromolecular and/or hydrophobic pharmaceutical substance to a patient comprising selective bolus delivery of substance intradermally **to achieve a substantially higher C_{max} and/or a substantially shorter T_{max} and/or a substantially shorter time to reach a threshold blood serum concentration of pharmaceutical effect of the substance**, classified in class 604, subclass 507.

Group IV: **Claims 53-59**, drawn to a method for delivering a bioactive substance to a subject comprising the steps of **contacting the skin of the subject with a device having a dermal access means for accurately targeting the dermal space of the subject, wherein the pharmacokinetics of the bioactive substance is improved relative to the pharmacokinetics of the substance when administered subcutaneously**, classified in class 604, subclass 518.

Group V: Claims 60-66, drawn to a method for delivering a bioactive substance comprising contacting the skin of the subject with a device having a dermal access means for accurately targeting the dermal space of the subject with an efficacious amount of the bioactive substance at a rate of 1nL/min to 200 mL/min and delivering the substance into the dermis over a time period of no more than ten minutes, classified in class 604, subclass 502.

The Examiner contends that the inventions of Groups I-V are distinct because they are related as subcombinations disclosed as usable together in a single combination. The Examiner further contends that the inventions have separate utility in view of the limitations highlighted in each one of the groups.

In response, Applicants elect with traverse the invention of Group III, Claims 31-52, to prosecute in the present application without prejudice to prosecute the subject matter of the non-elected Groups in one or more subsequent divisional applications.

Entry of the foregoing amendments and consideration of the remarks is respectfully requested. The claims are believed to be patentable and free of the art. Early allowance is respectfully requested.

by *Jaqueline Benn*
Reg No. 43,492

Date June 28, 2004

Laura A. Coruzzi 30,742
Laura A. Coruzzi (Reg. No.)
JONES DAY
222 East 41st Street
New York, N.Y. 10017-6702
(212) 790-9090